REMARKS

Accompanying this filing are: a petition for a three-month extension of time; a Revocation of Power of Attorney and Appointment of New Attorney; and a copy of an Assignment and Recordal Cover Sheet evidencing the ownership interest of Haemonetics Corporation.

Below are detailed remarks addressing each objection/rejection raised in the Office Action dated May 17, 2004. No new matter has been added by the present amendment.

Claim Rejections - 35 U.S.C. § 112

Claim 1 has been amended to correct a typographical error. The word "of" has been added in line 1, before "a volume". A "volume of fluid containing red blood cells" is what is separated from the "solution". The heamtocrit is the percentage of the volume of fluid occupied by cells – Stedman's Medical Dictionary 24th edition, Wiliams & Wilkins, 1982). The present claims define that "volume of fluid" that is separated from the solution has a hematocrit of about 30-64.

"Solution" refers not just to the blood but the combination of the blood, washing fluid and anticoagulant. This is consistent with the language of independent claims 1 (amended), 5 and 6.

Claim Rejections - 35 U.S.C. § 102

1) Rejections based on Dorner

In response to the rejection of claims 1-3, 5-10 and 21-23 as anticipated by Dorner et al., "Efficacy of leucocyte-poor red blood cell suspensions prepared by sedimentation in hydroxyethyl starch", Transfusion 15 (5) : 439-48 (1975), applicants have amended claims 1, 5 and 6 to specify that the blood in the solution with the washing fluid and anticoagulant is shed blood. The methods of applicants' invention are especially useful in blood salvage procedures in which blood is collected from the patient, washed and red blood cells returned right back to the patient. Dorner mentions use only of stored blood or stored red blood cells in the methods discussed. Due to the likely metabolic differences between shed blood and stored blood, Dornrer's experiments can't be said to have direct relevance to applicants' invention.

Furthermore, Dorner states that the samples of blood taken before and after sedimentation were diluted to a hematocrit of 30-35 percent, apparently to prepare the samples for later testing (Dorner at page 440). Intentionally diluting samples to a hematocrit of 30-35 percent bears no relevance to applicants' claim limitation that the volume of fluid separated by sedimentation have a hematocrit of 30-64 (i.e. undiluted).

Based on the above amendments and comments Dorner should not be considered to anticipate claims 1-3, 5-10 and 21-23.

2) Rejections based on U.S. Pat. No. 4,765,899 (Wells et al.)

Applicants traverse the rejection of claims 1, 4-6, 11, 21-23. The passage in Wells cited in the action as anticipating the claims (example 1) clearly states that the blood used was diluted with HES in an ACD solution. In contrast, the entire purpose of the applicants' invention is to avoid the use of ACD in separating red blood cells.

In the action it was noted that; "when the applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicants' invention" (citing *In re DeLajarte*). From this portion of the action, applicants wish to draw the examiner's attention to language in the second cited case, *Ex parte Hoffman:* "To determine the steps included versus excluded the claim must be read in light of the specification...[I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language." In view of applicants' and adamant and repeated statements in the specification regarding the disadvantages of using ACD and the desire to find a new method of separation that does not use ACD, applicants' claims surely should be interpreted to exclude the uses ACD under the *In re Hoffman* standard.

In the specification at the first paragraph of the *Summary of the Invention,* It is stated:

> "Applicants have discovered that a serious obstacle in the prior

process is that the anticoagulant employed has a major effect on the viability of the process. Thus, applicants have discovered that a process wherein the anticoagulant mixed with the shed blood that is not the usual ACD-A provides remarkably improved results. That is, in accordance with the invention, a cell salvage process wherein shed blood is combined with only inert anticoagulants and then mixed with a washing solution having a reagent, such as hetastarch, successfully separates red blood cells in a gravity sedimentation method."

At the third paragraph of the Summary of the Invention applicants further state:

"Applicant believes that the prior art method was not useful because the anticoagulant used in the process, ACD-A, has an adverse effect on the red blood cells. In particular, it is now believed that the absorption of ACD-A by the red blood cells has a physical effect on the cells that prevents them from forming the desired rouleau and settling out under gravitational forces as desired. One theory developed by applicants is that the absorption of ACD-A changes the shape of the red blood cells, swelling them and hindering their ability to form the rouleau. Other reasons for interference by the anticoagulant may exist."

Where the applicants have deliberately stated in the specification that the use of ACD is a serious obstacle in the success of the sedimentation process and that

applicants believe that ACD had an adverse effect on the very red blood cells that are being collected, there should be no question that the claimed inventive methods exclude the use of ACD. Accordingly, applicants request that the rejections based on Wells be withdrawn.

Claim Rejections - 35 U.S.C. § 103

The obviousness rejections based on U.S. Pat No. 5,879,318 (Van der Heiden) in view of Dorner should be withdrawn for several reasons. First, applicants continue to traverse rejections based on Van der Heiden because the reference clearly uses centrifugation in the disclosed process. Centrifugation changes the dynamics of separation so significantly due to the strong separation forces introduced that it cannot reasonably be assumed that a sedimentation process that otherwise follows the parameters of the centrifuge process would work just as effectively for separation.

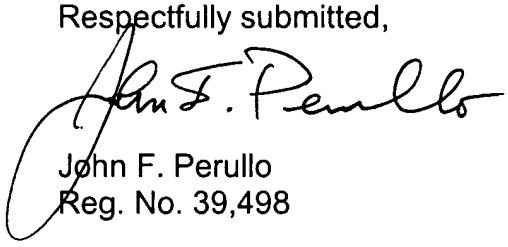
Second, neither Dorner nor Van der Heiden deal with separation from shed blood as now defined in the claims. The present invention deals with separation of red blood cells from blood collected from a live patient for the purpose of returning the separated cells right back to the patient. Dorner does not disclose separation involving shed blood as was discussed above. Van der Heiden also does not address separation involving shed blood to return red blood cells back to a patient in the manner of applicants' invention, but rather focuses on separating red cells to purify blood collected from an umbilical cord with the ultimate purpose of collecting stem cells. Indeed, Van der Heiden himself distinguishes his process from process where the blood donor is a

living person (see col. 2 lines 56-67).

Because Van der Heiden discloses only centrifugation, and neither Dorner nor Van der Heiden disclose a process using shed blood, the obviousness rejections should be withdrawn.

If there are any charges or any credits, please apply them to Deposit Account No. 50-3067.

Respectfully submitted,



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